

REMARKS

Applicant has reviewed and considered the Office Action dated August 13, 2003 and the references cited therein. In response thereto, claim 1 is canceled, claims 2-9 are amended, and new claims 10- are added. As a result, claims 2- are pending in the present application. Reconsideration is requested.

Objected to Claims

Claims 4-9 were objected to under 37 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claims 3-9 have been amended to remove the multiple dependencies.

Rejections Under 35 U.S.C. § 102

Claims 1-3 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hirsch (US 3,352,306), and claims 1 and 3 were rejected under 35 U.S.C. § 102(b) as being anticipated by Purdy et al. (EP 0 824 932). Claims 1 and 3 were also rejected under 35 U.S.C. § 102(e) as being anticipated by Luther (US 4,790,817), and claims 1-3 were rejected under 35 U.S.C. § 102(e) as being anticipated by Brimhall et al. (US 5,810,780). Applicant respectfully traverses these rejections for the following reasons.

Claim 1 has been canceled without prejudice or disclaimer. Claims 2-9 are dependent on new claim 10. Claim 10 recites a cannula/needle combination of a catheter head for administering a fluid substance, comprising a needle and a cannula surrounding the needle in a snug fit between an inner wall of the cannula and an outer wall of the needle, wherein a clearance is configured between the inner wall of the cannula and the outer wall of the needle and the fluid substance is communicated in the clearance without the needle being necessarily hollow.

Hirsch discloses an intravenous catheter assembly wherein a cannula is inserted using a stylet which is removed after the cannula is in place. The assembly has a fitting (14) to fit between the catheter (1) and the plug (4). As shown in Figs. 17-20, the needle (n) is mounted

onto the fitting (14). Hirsch does not disclose or teach that a cannula surrounding a needle wherein there is a snug fit for communicating a substance between an inner wall of the cannula and an outer wall of the needle. Rather, as shown in Figs. 17, 19 and 20 of Hirsch, the inner wall of a catheter is not described in terms of its relationship with an outer wall of a needle. In fact, it is the fitting (14) that is configured to be in a snug fit with the needle (column 6, lines 33-38), not the inner wall of a cannula and the outer wall of a needle as recited in claim 10. For at least this reason, applicant respectfully submits that claim 10 is not anticipated or made obvious by Hirsch.

Purdy discloses an arterial catheter and catheter/needle assembly with improved flow characteristics and method for its use. More particularly, as described in Purdy on page 4, lines 20-21, inserter needle (34) has a hub (42) attached at proximal end (36) that is sized to releasably fit within hub (26) of arterial catheter (11). Prudy does not disclose or teach a cannula surrounding a needle in a snug fit for communicating a substance between an inner wall of the cannula and an outer wall of the needle as recited in claim 10. Further, Prudy fails to disclose or teach that a clearance is configured between the inner wall of the cannula and the outer wall of the needle, whereby the fluid substance is communicated in the clearance along the catheter head without the needle being necessarily hollow as recited in claim 10. As disclosed in Purdy, at page 4, lines 32-34, when the catheter (11) is flexed or bent inward, projections (28) are of sufficient size and shaped to engage each other and maintain a fluid flow path through the bore (24). Thus, Applicant respectfully submits that claim 10 is not anticipated or taught by Purdy.

Luther discloses an assembly of a stylet and catheter, and a needle and catheter. More particularly, as described in column 1, lines 15-20, Luther relates to a stylet providing an axially aligned puncture tip, the stylet being inserted through a catheter to form an assembly which can effectively pierce a vein. Upon withdrawal of the stylet, the catheter remains in place in the vein. As further disclosed in Luther, in operation, the stylet and catheter are inserted into a vein, artery, organ, or the like. If the catheter is to remain in place in the vein when the stylet is withdrawn, the proximal end of the catheter must be dislodged from the position against the proximal shoulder of the stylet when the stylet tip is still located in the vein. When the stylet is inserted into the vein, contact of the catheter with blood will cause the catheter tip to expand out of contact from the shoulder of the stylet. When the stylet is retracted, the catheter will remain in

place in the user's vein (Luther, column 5, lines 5-17). Accordingly, Luther does not disclose or teach that clearance is configured between the inner wall of the cannula and the outer wall of the needle such that in use, a fluid substance is communicated in the clearance. To the contrary, in Luther's operation, the stylet is withdrawn, and the fluid substance is communicated within separate feed bores of the catheter (Figs. 11-16, column 3, lines 19-22; column 5, lines 18-39), not within a clearance between the inner wall of the catheter and the outer wall of the stylet. For at least this reason, Applicant respectfully submits that claim 10 is patentably distinguishable over Luther.

Brimhall discloses a multiple cross section needle and elastic plug assembly for a medical device. More particularly, Brimhall discloses a hollow needle (40) including a notch (42) that allows blood to flow therethrough and into the annular space between the needle and the catheter (20) (Brimhall, column 4, lines 29-30). However, the path of the blood flow is through lumen (46), not through the clearance space between the inner wall of the cannula and the outer wall of the needle. Accordingly, Brimhall fails to disclose or teach that clearance is configured between the inner wall of the cannula and the outer wall of the needle such that the fluid substance is communicated in the clearance along the catheter head without the needle being necessarily hollow. Accordingly, Applicant respectfully submits that claim 10 is patentable over Brimhall.

The remaining claims, claims 2-13 are dependent from claim 10 and are also patentable over the cited references for at least the reasons stated above.

Conclusion

This communication does not generate any new claim fees. Applicant encloses herewith a Petition to extend the time to respond from November 13, 2003 until February 13, 2004, along with a check in the amount of \$950.00. The Office is also hereby authorized to charge any deficiency associated with this communication or the Petition to Deposit Acct. 04-1420.

In view of the above amendments and preceding remarks, it is respectfully submitted that the application is in condition for allowance, and reconsideration is respectfully requested. If a telephone conference would be helpful in resolving any remaining issues, the Examiner is invited to call the undersigned.

Respectfully submitted,

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Date:

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